Bobby Jindal
GOVERNOR

Alan Levine
SECRETARY

State of Louisiana

Department of Health and Hospitals
Bureau of Health Services Financing

Clinical Laboratory Improvement Amendments of 1988 (CLIA)
SURVEY INFORMATIONAL PACKET

Dear Laboratory Director:

Our records indicate that your facility holds a Clinical Laboratory Improvement Amendments (CLIA) of 1988 certificate of compliance that is due for survey during the next few months. This pre-survey packet is to inform you of the pending survey and to provide you with information that will help prepare you. If you feel that this survey is in error due to a status change at your facility, please contact our office immediately to rectify the discrepancy. Otherwise, a representative from the Louisiana State Agency will be contacting you at a later date to schedule an onsite certification survey for the Centers for Medicare & Medicaid Services (CMS) for CLIA purposes.

The CMS-2226-F 42 CFR 493 Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications Final Rule was published on January 24, 2003 *Vol. 68 Federal Register 3640* and became effective April 24, 2003. The majority of the material contained in this regulation was merely a reorganization of existing provisions, but there are a limited number of new provisions in the rule as well. We encourage you and your staff to familiarize yourselves with the new provisions. The New Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services is available at the CMS CLIA page: http://www.cms.hhs.gov/clia/ . During this survey cycle, CMS is seeking to educate providers about the new regulatory requirements, and hopes to obtain voluntary compliance with these requirements.

In order to facilitate the survey process, we request that you complete, sign, and hold on to the following forms until the onsite survey:

1. Disclosure of Ownership
2. CMS-209 (Laboratory Personnel Report) - sign and date the original; use the photocopy to list your personnel, positions, & status.
3. Form CMS-116 including the attachment page listing all tests (waived/PPMP/moderate and/or high complexity) performed in your laboratory with the annual total volumes for each test. (PPMP = Provider Performed Microscopy Procedures)
4. Also have the following available: Federal tax ID#, Medicare #, Medicaid #, and Fiscal year end date.
5. Task Sheet 1 & 3

We request the following information be accessible and retrievable at the time of the survey:

1. Standard Operating Procedure Manual with all test procedures (e.g. package inserts and supplemental information, as necessary);
2. Reference laboratories' client services manual, if applicable;
3. Records of tests referred to other laboratories;
4. Personnel records, including:
    a. Diplomas, certificates, degrees;
    b. Training, and experience; Continuing education
    c. Competency assessment

d. Duties/responsibilities; and
e. Personnel changes.

5. Quality control records, including:
    a. Remedial action information;
    b. Calibration and calibration verification records;
    c. Statistical limits; and
    d. Instrument maintenance and function checks records.
6. Proficiency testing (PT) reports, including:
    a. Test runs with PT results
    b. Direct printouts; and
    c. Remedial actions for unsatisfactory results.
7. Quality system assessment plans and documentation (Preanalytical, Analytical, and Post-analytical):
    a. policies and procedures to monitor,assess, and correct identified problems;
    b. documentation of ongoing assessment activities, including
        i. review of the effectiveness of corrective actions taken
        ii. revision of policies and procedures to prevent recurrence of problems; and
        iii. discussion of assessment reviews with staff.
8. Safety information; and
9. Patient testing records:
    a. Requisitions (patient charts may be used)
    b. Work records (direct printouts); and
    c. Patient test reports (patient charts may be used).

The onsite survey of your laboratory will be preceded by an entrance interview to identify the surveyor(s) and to explain the Outcome-Oriented Survey Process. The surveyor(s) will review and assess the overall functioning of the laboratory and evaluate the laboratory's quality system. The surveyor will select a cross-section of information from all aspects of the laboratory's operation for review to assess the laboratory's ability to provide quality laboratory test results.

If you have any questions about your impending survey or the directives contained in this correspondence, please call me at (225) 342-9324.

Sincerely,

Staci B. Glueck, BSMT(ASCP)
CLIA Program Manager

Enclosure

SURVEY PROCESS SUMMARY

The survey is conducted using established Centers for Medicare & Medicaid Services (CMS) guidelines. The survey process is outcome oriented and will consist of the following:

- Entrance Interview – for the identification of the surveyor(s) and to explain the survey process
- Tour and assessment of the facilities
- Verification of proficiency testing enrollment, testing, and review of results
- Evaluation and Quality Assessment Program
- Sample selection, personnel interview and record review (see **Sample Selection below)
- Assessment of specimen integrity; observations of skills and abilities of testing and supervisory staff; evaluation of equipment and testing supplies
- Assessment of test performance and reporting of results
- Verification of personnel qualifications
- Analysis and evaluation of findings
- Exit Conference – to inform the facility's staff of the observations and findings and to solicit additional information from the facility in response to the surveyor's findings

**Survey Sample (Record) Selection – A sample of patient test records will be selected that will reflect the laboratory's ability to provide quality testing from all areas of the laboratory including records encompassing the time period since the last certification survey for recertification surveys or the inception of the CLIA certificate for initial surveys. Therefore, the survey sample could include each test performed in the facility and cover the previous two years of testing. In order to complete this task, it will be necessary for the laboratory to provide the surveyor(s) with the patient test accession log or provide a listing of test procedures by patient performed on a daily basis. The process of sample selection cannot be outlined in a single set of guidelines, but is individualized for each different situation while complying with CMS survey guidelines.

The sample will be initially identified and then may be adjusted as the survey process proceeds. That is, if all findings are consistent and no problem(s) are identified, all records may not be reviewed. However, if a problem is identified then all record in the problem area will be reviewed and if needed, additional records may be requested.

Records required for this phase of the survey include:

- Copy of test requisitions
- Copy of test report
- Test work sheets or logs utilized by the laboratory to record or document daily test performance including the identification of the lot numbers, expiration dates, dates placed into use of reagents, controls, stains and/or calibrators used on the day sampled for each procedure. Also includes instrument printouts.
- Quality control records for the sample day and documentation of the evaluation of control results along with remedial action information
- Instrument maintenance records
- Calibration records

DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT

I. Identifying Information

(a) Name of Entity	D/B/A	Provider No.	Telephone No.
Street Address		City, County, State	Zip Code

II. Answer the following questions by checking "Yes" or "No." If any of the questions are answered "Yes," list names and addresses of individuals or corporations under Remarks on page 2. Identify each item number to be continued.

(a) Are there any individuals or organizations having a direct or indirect ownership or control interest of 5 percent or more in the institution, organizations, or agency that have been convicted of a criminal offense related to the involvement of such persons, or organizations in any of the programs established by titles XVIII, XIX, or XX?

□ Yes □ No

(b) Are there any directors, officers, agents, or managing employees of the institution, agency or organization who have ever been convicted of a criminal offense related to their involvement in such programs established by titles XVIII, XIX, or XX?

□ Yes □ No

(c) Are there any individuals currently employed by the institution, agency, or organization in a managerial, accounting, auditing, or similar capacity who were employed by the institution's, organization's, or agency's fiscal intermediary or carrier within the previous 12 months?

□ Yes □ No

III. (a) List names, addresses for individuals, or the EIN for organizations having direct or indirect ownership or a controlling interest in the entity. (See instructions for definition of ownership and controlling interest.) List any additional names and addresses under "Remarks" on page 2. If more than one individual is reported and any of these persons are related to each other, this must be reported under Remarks or as an attachment.

Name	Address	EIN

(b) Type of Entity: □ Sole Proprietorship □ Partnership □ Corporation
□ Unincorporated Associations □ Other (Specify)_____

(c) If the disclosing entity is a corporation, list names, addresses of the Directors, and EINs for corporations under Remarks.

Check appropriate box for each of the following questions:

(d) Are any owners of the disclosing entity also owners of other Medicare/Medicaid facilities? (Example: sole proprietor, partnership or members of Board of Directors.) If yes, list names, addresses of individuals and provider numbers.

□ Yes □ No

Name_____

Address_____

Provider Number_____

IV (a) Has there been a change in ownership or control within the last year? □ Yes □ No
If yes, give date _____

(b) Do you anticipate any change of ownership or control within the year? □ Yes □ No

if yes, when?_____

V. is this facility operated by a management company, or leased in whole or part by another organization?

□ Yes □ No

If yes, give date of change in operations_____

VI. Has there been a change in Laboratory Director within the last year? □ Yes □ No

Current Director:_____

VII. (a) Is this facility chain affiliated? (If yes, list name, address of Corporation, and EIN)

Name and address	EIN # (TAX ID)

VII. (b) If the answer to Question Vll.a. is No, was the facility ever affiliated with a chain? (If yes, list Name, Address of Corporation, and EIN)

Name and address	EIN # (TAX ID)

WHOEVER KNOWINGLY AND WILLFULLY MAKES OR CAUSES TO BE MADE A FALSE STATEMENT OR REPRESENTATION OF THIS STATEMENT, MAY BE PROSECUTED UNDER APPLICABLE FEDERAL OR STATE LAWS. IN ADDITION, KNOWINGLY AND WILLFULLY FAILING TO FULLY AND ACCURATELY DISCLOSE THE INFORMATION REQUESTED MAY RESULT IN DENIAL OF A REQUEST TO PARTICIPATE OR WHERE THE ENTITY ALREADY PARTICIPATES, A TERMINATION OF ITS AGREEMENT OR CONTRACT WITH THE STATE AGENCY OR THE SECRETARY, AS APPROPRIATE.

Name of Authorized Representative (Typed/Printed)_____

Title_____

Signature_____

Date_____

Remarks

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0151

LABORATORY PERSONNEL REPORT (CLIA)

(For moderate and high complexity testing)

1. LABORATORY NAME		2. CLIA IDENTIFICATION NUMBER
3. LABORATORY ADDRESS *(NUMBER AND STREET)*	CITY	STATE / ZIP CODE

4. Instructions:
a. List below all technical personnel, by name, who are employed by the laboratory. Check (✔) the appropriate column for each position held. For TC and TS follow instructions on reverse.
b. Indicate whether shift worked is (1) day, (2) evening or (3) night.
c. Indicate highest level of testing for which personnel are qualified: Use (M) for moderate and (H) for high complexity.
d. Indicate whether position held is full (F) or part-time (P).

Positions:
D-Director
CC - Clinical Consultant
TC - Technical Consultant
TS - Technical Supervisor
GS - General Supervisor
TP- Testing Personnel
CT/GS - Cytology General Supervisor
CT - Cytotechnologist

5. TELEPHONE *(INCLUDE AREA CODE)*

FOR OFFICIAL USE ONLY
(NOT TO BE COMPLETED BY LABORATORY)
QUALIFIES ACCORDING TO SUBPART M

DATE OF SURVEY _____

EMPLOYEE NAMES			a. POSITION HELD								b. SHIFT 1 2 3	c. M OR H	d. F OR P
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT			

❑ Check (✔) here if additional space is needed to list all technical personnel. Copy this page and attach continuation sheet(s) to the original form.

READ THE FOLLOWING CAREFULLY BEFORE SIGNING

Statement or Entities Generally: Whoever, in any manner within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001)

CERTIFICATION: I CERTIFY THAT ALL OF THE INDIVIDUALS LISTED ABOVE QUALIFY, TO FUNCTION IN THE POSITION INDICATED, ACCORDING TO THE PERSONNEL REGULATIONS OF 42 CFR PART 493 SUBPART M.

6. SIGNATURE OF LABORATORY DIRECTOR	7. DATE

INSTRUCTIONS FORM CMS-209

This form will be completed by the laboratory. It will be used by the surveyor to review the qualifications of technical personnel in the laboratory.

Instructions for 4(a) TC/TS:
When listing those individuals holding technical consultant/technical supervisor (TC/TS) positions, use the following grid to indicate the specialty(ies)/subspecialty(ies) in which they presently function. Record the number corresponding to the specialty/subspecialty in the appropriate column (TC/TS). When an individual functions as a TC/TS in more than one specialty/subspecialty, use a line for each specialty/subspecialty.

GRID:

1. Bacteriology
2. Mycobacteriology
3. Mycology
4. Parasitology
5. Virology
6. Diagnostic Immunology
7. Chemistry
8. Hematology
9. Immunohematology
10. Clinical Cytogenetics
11. Histocompatibility
12. Radiobioassay
13. Histopathology
14. Oral Pathology
15. Cytology
16. Dermatopathology
17. Ophthalmic Pathology

EXAMPLE

EMPLOYEE NAMES			a. POSITION HELD								b. SHIFT 1 2 3	c. M OR H	d. F OR P
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT			
Smith	John				1						1	M	F
						4						H	
						6						H	

FOR OFFICIAL USE ONLY

Indicate the applicable regulatory citation under which the following individuals are qualified: Each laboratory director, technical consultant, technical supervisor, clinical consultant, general supervisor, cytology supervisor, and those testing personnel and cytotechnologist sampled during the survey process.

TASK 1 and 3

CLIA ID _____

Specialty / Subspecialty	Analytes Tested	High/ Mod	Annual Volume	Instrument/Method Used	Control Material Utilized	Manufacturer's Instructions	Other

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

❑ Initial Application ❑ Survey ❑ Change in Certification Type ❑ Other Changes	CLIA Identification Number _____D_____ *(If an initial application leave blank, a number will be assigned)*
Facility Name	Federal Tax Identification Number Telephone No. *(Include area code)* Fax No. *(Include area code)*
Facility Address — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified*	Mailing/Billing Address ***(If different from street address, include attention line and/or Building, Floor, Suite)***
Number, Street *(No P.O. Boxes)*	Number, Street
City State ZIP Code	City State ZIP Code
Name of Director *(Last, First, Middle Initial)*	For Office Use Only Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *(Check one)*

❑ Certificate of Waiver *(Complete Sections I – VI and IX – X)*

❑ Certificate for Provider Performed Microscopy Procedures *(PPM) (Complete Sections I – X)*

❑ Certificate of Compliance *(Complete Sections I – X)*

❑ Certificate of Accreditation (Complete Sections I through X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes

❑ The Joint Commission ❑ AOA ❑ AABB
❑ CAP ❑ COLA ❑ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ❑ 01 Ambulance
- ❑ 02 Ambulatory Surgery Center
- ❑ 03 Ancillary Testing Site in Health Care Facility
- ❑ 04 Assisted Living Facility
- ❑ 05 Blood Bank
- ❑ 06 Community Clinic
- ❑ 07 Comp. Outpatient Rehab Facility
- ❑ 08 End Stage Renal Disease Dialysis Facility
- ❑ 09 Federally Qualified Health Center
- ❑ 10 Health Fair
- ❑ 11 Health Main. Organization
- ❑ 12 Home Health Agency
- ❑ 13 Hospice
- ❑ 14 Hospital
- ❑ 15 Independent
- ❑ 16 Industrial
- ❑ 17 Insurance
- ❑ 18 Intermediate Care Facility for Mentally Retarded
- ❑ 19 Mobile Laboratory
- ❑ 20 Pharmacy
- ❑ 21 Physician Office
- ❑ 22 Practitioner Other *(Specify)* _____
- ❑ 23 Prison
- ❑ 24 Public Health Laboratories
- ❑ 25 Rural Health Clinic
- ❑ 26 School/Student Health Service
- ❑ 27 Skilled Nursing Facility/ Nursing Facility
- ❑ 28 Tissue Bank/Repositories
- ❑ 29 Other *(Specify)* _____

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed in HH:MM format)*

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision)*

Are you applying for the multiple site exception?

❑ No. If no, go to section VI. ❑ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?
   ❑ Yes ❑ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
   ❑ Yes ❑ No

   If yes, provide the number of sites under the certificate_____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
   ❑ Yes ❑ No

   If yes, provide the number of sites under this certificate_____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ❑ and attach the additional information using the same format.

NAME AND ADDRESS / LOCATION		TESTS PERFORMED / SPECIALTY / SUBSPECIALTY
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Indicate the estimated TOTAL ANNUAL TEST volume for all waived tests performed _____

❑ Check if no waived tests are performed.

VII. PPM TESTING

Indicate the estimated TOTAL ANNUAL TEST volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the "total estimated test volume" in section VIII.

❑ Check if no PPM tests are performed

VIII. NONWAIVED TESTING *(Including PPM testing)*

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY		_____	**HEMATOLOGY**		_____
❑ Transplant	_____		❑ Hematology	_____	
❑ Nontransplant	_____				
			IMMUNOHEMATOLOGY		_____
MICROBIOLOGY		_____	❑ ABO Group & Rh Group	_____	
❑ Bacteriology	_____		❑ Antibody Detection (transfusion)	_____	
❑ Mycobacteriology	_____		❑ Antibody Detection (nontransfusion)	_____	
❑ Mycology	_____		❑ Antibody Identification	_____	
❑ Parasitology	_____		❑ Compatibility Testing	_____	
❑ Virology	_____				
DIAGNOSTIC IMMUNOLOGY		_____	**PATHOLOGY**		_____
❑ Syphilis Serology	_____		❑ Histopathology	_____	
❑ General Immunology	_____		❑ Oral Pathology	_____	
			❑ Cytology	_____	
CHEMISTRY		_____			
❑ Routine	_____		**RADIOBIOASSAY**		_____
❑ Urinalysis	_____		❑ Radiobioassay	_____	
❑ Endocrinology	_____				
❑ Toxicology	_____		**CLINICAL CYTOGENETICS**		_____
			❑ Clinical Cytogenetics	_____	

TOTAL ESTIMATED ANNUAL TEST VOLUME _____

IX. TYPE OF CONTROL

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT	
01 Religious Affiliation	04 Proprietary	05 City	08 Federal
02 Private		06 County	09 Other Government
03 Other _____ *(Specify)*		07 State	_____ *(Specify)*

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*	DATE

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing nonwaived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be provided and submitted with the application. Information to be submitted with the application include:

- **Verification of State Licensure, as applicable**
- **Documentation of qualifications:**
  - **Education (copy of Diploma, transcript from accredited institution, CMEs),**
  - **Credentials, and**
  - **Laboratory experience.**

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "Change in certificate type". For all other changes, including change in location, director, etc., check "other changes".

For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. Be specific when indicating the name of your facility, particularly when it is a component of a larger entity; e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. **NOTE: The information provided is what will appear on your certificate.**

Facility street address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable. **DO NOT USE A POST OFFICE BOX NUMBER OR A MAIL DROP ADDRESS FOR THE NUMBER AND STREET OF THE ADDRESS.** If the laboratory has a separate mailing address, please complete that section of the application.

NOTE: For Office Use Only—Date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

When completing this section, please remember that a facility holding a—

- **Certificate of Waiver** can only perform tests categorized as waived;*
- **Certificate for Provider Performed Microscopy Procedures** (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the laboratory is currently accredited by an approved accreditation organization.**

*A current list of waived and PPMP tests may be obtained from your State agency. Specific test system categorizations can also be reviewed via the Internet on *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm.*

**If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

III. TYPE OF LABORATORY

Select the type of laboratory designation that is most appropriate for your facility from the list provided. If you cannot find your designation within the list, contact your State agency for assistance.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493.

VI. WAIVED TESTING

Indicate the estimated total annual tests volume for all waived tests performed.

VII. PPM TESTING

Indicate the estimated annual test volume for all PPM tests performed.

VIII. NON-WAIVED TESTING *(INCLUDING PPM)*

The total volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL

Select the type which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible.

Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALTIES

HISTOCOMPATABILITY
HLA Typing (disease associated antigens)

SYPHILIS SEROLOGY
RPR
FTA, MHATP

GENERAL IMMUNOLOGY
Mononucleosis Assays
Rheumatoid Arthritis
Febrile Agglutins
Cold Agglutinins
HIV
Antibody Assays (hepatitis, herpes, etc.)
ANA Assays

PARASITOLOGY
Direct Preps
Ova and Parasite Preps
Wet Preps

CHEMISTRY
Routine Chemistry
Albumin
Ammonia
Alk Phos
Bilirubin, Total
Bilirubin, direct
Calcium
Chloride
CO2, total
Ferritin
Glucose
Iron
Magnesium
pH
pO2
pCO2
PSA
Sodium
Vitamin B12
ALT/SGPT
AST/SGOT
Amylase
BUN
CK/CK isoenzymes
Cholesterol, total
Creatinine
Folate
HDL Cholesterol
LDH
LDH isoenzymes
Phosphorous
Potassium
Protein, total
GGT
Troponin
Triglycerides
Uric acid

Urinalysis
Automated urinalysis
Urinalysis with microscopic analysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfasalicylic acid

BACTERIOLOGY
Gram Stains
Cultures
Sensitivities
Strep Screens
Antigen assays
(H. pylori, Chlamydia, etc.)

MYCOBACTERIOLOGY
Acid Fast Smears
Mycobacterial Cultures
Mycobacterial Sensitivities

MYCOLOGY
Fungal Cultures
DTM
KOH Preps

VIROLOGY
RSV
HPV assays
Cell cultures

Endocrinology
TSH
Free T4
Total T4
Trilodothyronine (T3)
Serum-beta-HCG

Toxicology
Acetaminophen
Blood alcohol
Carbamazephine
Digoxin
Ethosuximide
Gentamycin
Lithium
Phenobarbitol
Phenytoin
Primidine
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Valproic acid

HEMATOLOGY

WBC count
RBC count
Hemoglobin
Hematocrit (Other than spun micro)
Platelet count
Differential
Activated Clotting Time
Prothrombin time
Partial thromboplastin time
Fibrinogen
Reticulocyte count
Manual WBC by hemocytometer
Manual platelet by hemocytometer
Manual RBC by hemocytometer
Sperm count

RADIOBIOASSAY

Red cell volume
Schilling's test

IMMUNOHEMATOLOGY

ABO group
Rh(D) type
Antibody Screening
Antibody Identification
Compatability testing

PATHOLOGY

Dermatopathology
Oral pathology
PAP smear interpretations
Other cytology tests
Histopathology

CYTOGENETICS

Fragile X
Buccal smear

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- Testing for allergens should be counted as one test per individual allergen.
- For **chemistry** profiles, each individual analyte is counted separately.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **complete blood counts**, each **measured** individual analyte that is ordered **and reported** is counted separately. Differentials are counted as one test.
- Do not count calculations (e. g., A/G ratio, MCH, and T7), quality control, quality assurance and proficiency testing assays).
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- For **cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.
- For flow **cytometry** each measured individual analyte that is ordered and reported is counted separately.

QUALITY ASSESSMENT

Quality assessment (previously denoted as Quality Assurance) is an integral part of every laboratory system. Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. Therefore, QA is interspersed throughout the CLIA regulations which parallel the flow of a patient specimen through the testing process. QA requirements are present in the General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems. Following are the actual regulations regarding QA along with the interpretive guidelines to assist you in understanding your requirements as a laboratory:

§493.1239 Standard: General laboratory systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at §§493.1231 through 493.1236.

Interpretive Guidelines §493.1239(a)-(c)

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with responsibilities to patients, physicians, and other laboratories ordering tests, and the other non-laboratory areas or departments of the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

QA of the General Laboratory System includes assessing practices/issues related to:

- *Patient confidentiality;*
- *Specimen identification and integrity;*
- *Complaint investigations;*
- *Communications;*
- *Personnel competency; and*
- *Proficiency testing performance.*

An example would be monitoring the type and number of complaints received by the laboratory such as a particular client continuously complaining about the laboratory's failure to promptly respond to STAT test requests. The laboratory must have documentation that the complaint was investigated and appropriate action taken to correct the problem.

Verify that the laboratory has a system in place for monitoring and evaluating confidentiality of patient information.

Probes §493.1239(a)

How does the laboratory assure that an individual who had problems in performance is competent after appropriate retraining and technical assistance is completed?

How does the laboratory determine which complaints require investigation and which do not?

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff.

Interpretive Guidelines §493.1239(b)

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Probes §493.1239(b)

When problems are identified in personnel competency, what corrective actions are instituted to assist employees to improve performance?

When the laboratory identifies a problem, are corrective actions taken, the resolution documented and monitored for effectiveness?

How does the laboratory prevent reoccurrences of problems?

How does the laboratory document and identify potential communication problems and corrective actions taken (e.g., with staff, referral laboratories)?

Have the corrective actions taken as a result of failures in proficiency testing (PT) and/or verification of accuracy testing as required under subpart H, improved performance?

(c) The laboratory must document all general laboratory systems quality assessment activities.

Interpretive Guidelines §493.1239(c)

The steps taken by the laboratory to identify and correct problems, and prevent their recurrences must be documented. All laboratory policies amended due to its QA activities must be noted.

§493.1249 Standard: Preanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§493.1241 through 493.1242.

Interpretive Guidelines §493.1249(a)-(c)

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the other non-laboratory areas or departments of the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem. All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

*QA of the **Preanalytic System** includes assessing practices/issues related to test requests, specimen submission, handling and referral.*

Some examples include: monitoring the frequency of specimen handling problems (such as the use of an improper blood collection tube, inadequate mixing of blood specimens with anticoagulant after collection), and delays in specimen transport; identifying clients who repeatedly refer unacceptable specimens or improperly complete requisition forms and documentation of its efforts to reduce the recurrence of these problems.

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Probes §493.1249(a)-(c)

When a laboratory uses off-site drawing facilities, what policies or procedures does the laboratory use to ensure proper accountability or tracking of patient specimens from time of collection to receipt by the laboratory performing the tests?

Does the laboratory perform periodic or spot checks for accurate transfer of information

(e.g., manual entries by personnel from test orders to test requisition or into an LIS)? For referral specimens, how does the laboratory check for transcription errors when patient test information is transcribed from the laboratory's original requisition form to the reference laboratory's requisition?

What actions does the laboratory take if test requisitions from one or more clients are consistently incomplete, illegible or contain incorrect information?

What actions does the laboratory take if specimens received from one client are consistently unsatisfactory for testing (e.g., specimens for Cytology)? Has the laboratory's efforts to reduce the recurrence of these problems been documented and effective?

(b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all preanalytic systems quality assessment activities.

Interpretive Guidelines §493.1249(c)

The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must also be noted.

§493.1289 Standard: Analytic systems quality assessment.

Interpretive Guidelines §493.1289(a)-(c):

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the non-laboratory areas or the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

- *Test procedures;*
- *Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies;*
- *Specimen and reagent storage condition;*
- *Equipment/instrument/test/system maintenance and function checks;*
- *Establishment and verification of method performance specifications;*
- *Calibration and calibration verification;*
- *Control procedures;*
- *Comparison of test results;*
- *Test records.*
- *Corrective actions; and*

For Clinical Cytogenetics, cases, the laboratory should identify increases in or excessive culture failure rates, determine the contributing factors, document efforts to reduce or eliminate these factors and assess the effectiveness of actions taken. (i.e., a decrease in the culture failure rate).

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.

QA of the Analytic System includes assessing:

Select a sample of abnormal cytology patient reports and determine that, when available, the histopathology and cytology comparison was performed and the cytology 5-year retrospective review was performed. Ensure the laboratory documents any discrepancies and performs corrective action.

For International Normalized Ratio (INR) calculation, ensure the laboratory:

- *Periodically verifies, for each thromboplastin lot number in use, the correct normal prothrombin time mean and (the International Sensitivity Index (ISI) value are being used for calculating the INR value.*
- *Periodically verifies the accuracy of the INR calculation (manual, instrument or LIS).*
- *Verify the ISI used in the calculation correlates with the ISI specified in the reagent package insert. Select an abnormal low or abnormal high prothrombin time result and verify the calculation.*
- *Check the accuracy of normal Prothrombin time mean calculation (manual, instrument or LIS).*

Probes §493.1289(a):

Does the laboratory add additional maintenance procedures and/or function checks, when needed, to ensure accurate and reliable test results?

What is the laboratory's system for monitoring and evaluating test results for inconsistencies with patient information?

§493.1289 Standard: Analytic systems quality assessment.

Interpretive Guidelines §493.1289(b):

Verify that the laboratory has a system in place to monitor and evaluate test results for inconsistencies with patient information, and for correlation between test results. For example, a laboratory could multiply the hemoglobin result by a factor of 3, to see if the result is equal to the hematocrit. If the laboratory has auto-validation in it's Laboratory Information System (LIS), verify that the laboratory is taking steps to reduce the likelihood of sample-switching errors, for example, when the creatinine result is significantly different from the patient's previous creatinine test results, or if the MCV is significantly different from the patient's previous test results and the patient did not receive a blood transfusion.

Review quality control records to determine if the laboratory's monitoring efforts are detecting control failures, shifts, and trends. If the surveyor identifies previously undetected quality control failures or omission, then the laboratory's system for monitoring and evaluating quality control may not be adequate.

To verify Prothrombin time testing with INR calculations:

For clinical cytogenetics cases, does the laboratory monitor the frequency of culture failures and sub-optimal analyses?

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.

Probes §493.1289(b):

How does the laboratory address multiple failed or sub-optimal cultures that have been submitted from one client?

How does the laboratory use the review of all normal or negative gynecologic specimens received within the previous 5 years to assess the analytic system and communicate findings to the staff?

(c) The laboratory must document all analytic systems assessment activities.

Interpretive Guidelines §493.1289(c):

The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must also be noted.

§493.1299 Standard: Postanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in §493.1291.

Interpretive Guidelines §493.1299(a)-(c):

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and non-laboratory areas or departments of the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves investigation, identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

*QA of the **Postanalytic System** includes assessing practices/issues related to test reports. Examples include monitoring and evaluating the accuracy and completeness of the laboratory's test reports (i.e., patient information, test results, normal ranges, and the disposition of unacceptable specimens), and the laboratory's turn-around times and procedures for notification of test results e.g., routine tests, STATS, abnormal or panic values.*

Review a cross-section of patient test reports for accuracy of patient information, test results and normal ranges to verify that the laboratory is effectively monitoring and evaluating the quality and accuracy of the information supplied to its clients.

Verify that the laboratory has a system in place to monitor and evaluate its established reporting time frames and procedures for notification of test results, routine tests, STATS, abnormal or panic values.

If the laboratory uses an LIS, the laboratory must have a mechanism to periodically verify the accuracy of:

- *its calculated data;*
- *its results sent to interfaced systems; and*
- *patient specific data.*

§493.1299 Standard: Postanalytic systems quality assessment.

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff.

Interpretive Guidelines §493.1299(b):

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

(c) The laboratory must document all postanalytic systems quality assessment activities.

Interpretive Guidelines §493.1299(c):

The steps taken by the laboratory to identify and correct problems, and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must be noted.

Probes §493.1299(a)-(c):

What mechanism does the laboratory use to update and correlate the information to clients (e.g., client reference manuals), procedure manuals, reporting systems (e.g., LIS) when the laboratory introduces a new test system with different normal/reference range?

10 STEPS TO A QUALITY ASSESSMENT PROGRAM

Following is a general outline to assist you in developing a comprehensive quality assessment program.

1. EVALUATE SCOPE OF CARE

   (What do we do?)

2. IDENTIFY MAJOR ASPECTS OF CARE

   (What is most important?)

3. DEVELOP INDICATORS

   (What should we measure?)

4. ESTABLISH THRESHOLDS

   (What is acceptable? And What is not?)

5. ASSIGN RESPONSIBILITY

   (Who will do the monitoring?)

6. GATHER DATA & REPORT INFORMATION

   (What do we do with all this information?)

7. EVALUATE THE DATA

   (Did you find what you expected?)

8. CORRECTIVE ACTION

   (What should we do about it?)

9. COMMUNICATE INFORMATION

   (Does everyone know?)

10. MONITOR FOR SUSTAINED EFFECTIVENESS

    (Did it work?)

QUALITY ASSESSMENT IN THE TOTAL TESTING PROCESS